UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re SANOFI-AVENTIS SECURITIES LITIGATION	:	Civil Action No. 1:07-cv-10279-GBD
	:	CLASS ACTION
This Document Relates To:	:	
ALL ACTIONS.	:	

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR A LETTER OF REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE PURSUANT TO THE HAGUE CONVENTION OF 18 MARCH 1970 ON TAKING OF EVIDENCE ABROAD IN CIVIL OR CRIMINAL MATTERS

I. INTRODUCTION

Pursuant to the Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, Mar. 18, 1970, 23 U.S.T. 2555, T.I.A.S. No. 7444 (the "Hague Convention"), plaintiffs City of Edinburgh Council of the Lothian Pension Fund and New England Carpenters Guaranteed Annuity Funds ("plaintiffs") respectfully request that the Court issue a Letter of Request to the appropriate authority of The United Kingdom, for the purpose of obtaining documents from non-party the European Medicines Agency ("EMA"). *See also* 28 U.S.C. §1781. Because the EMA is a foreign entity located in England it cannot be compelled to produce documents in the United States. Therefore, the issuance of a Letter of Request under the procedures of the Hague Convention is the only feasible means for plaintiffs to obtain this evidence for this proceeding. The Letter of Request must be issued by a court in the country of origin (here, the United States District Court for the Southern District of New York). The Letter of Request complies with the procedures of the Hague Convention and is attached to the Declaration of Laurie L. Largent in Support of Plaintiffs' Motion for Letter of Request for International Judicial Assistance Pursuant to the Hague Convention of 18 March 1970 on Taking of Evidence Abroad in Civil or Criminal Matters ("Largent Decl.") submitted concurrently herewith, as Exhibit A. *See* Hague Convention, Ch. 1, Art. 1 (*see* 23 U.S.T. 2555).

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Relevant Factual Background[1]

This class action concerns defendants' violations of §§10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by the Securities and Exchange Commission ("SEC"), during the period of February 20, 2006 through June 13, 2007 (the "Class

[1] The facts are based on the allegations in Plaintiffs' First Amended Complaint for Violation of Securities Laws ("Complaint") (Docket #64).

Period"), when defendants Sanofi-Aventis SA ("Sanofi" or the "Company") and certain executive officers (the "Individual Defendants")[2] are alleged to have made public misstatements and material omissions concerning the development of the drug rimonabant and Sanofi's New Drug Application ("NDA") filed with the United States Food and Drug Administration ("FDA") for the use and marketing of rimonabant as a treatment for obesity in the United States. Sanofi marketed rimonabant as "Acomplia" in Europe from 2006 until the EMA withdrew marketing authorization for the drug in early 2009.

The Complaint alleges that during the Class Period defendants withheld material information from investors about rimonabant's risk profile by not disclosing that studies from the drug's clinical trials showed an increased risk of suicidality for patients taking rimonabant. The Complaint also alleges that during the Class Period defendants did not disclose that the FDA expressed concern about the link between rimonabant and suicidality and required Sanofi to get an independent assessment of the drug's safety based on the FDA's concern. According to plaintiffs, the independent assessment confirmed a statistically significant link between rimonabant and suicidality. Defendants, however, did not publicly disclose this information.

On June 13, 2007, the FDA disclosed the suicidality information about rimonabant. Based on this information, the FDA's advisory committee unanimously recommended that the FDA deny

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[2] The Individual Defendants are: Jean-Francois Dehecq, Sanofi's former CEO; Gerard LeFur, Sanofi's former Senior Vice President of Scientific and Medical Affairs and former CEO; Jean Claude Leroy, Sanofi's PFO and Executive Vice President of Finance and Legal; Hanspeter Spek, Sanofi's Executive Vice President of Pharmaceutical Operations; Marc Cluzel, Sanofi's Senior Vice President of Development and Scientific Affairs; and Douglas Greene, Sanofi's Vice President of Development and Scientific Affairs and Chief Medical Officer of Sanofi-U.S.

Sanofi's rimonabant application. As a result of this disclosure, the price of Sanofi's securities dropped sharply, causing investors significant losses.

III. ARGUMENT

A. A Letter of Request Is the Proper Method for Obtaining Documents from the EMA

The issuance of a Letter of Request seeking foreign judicial assistance in collecting evidence is authorized under the Hague Convention. The United States and the United Kingdom have signed this international treaty and are bound by its provisions as "Contracting States." *See* Hague Convention (23 U.S.T. 2555). *See also* 28 U.S.C. §1781; *Societe Nationale Industrielle Aerospatiale v. United States Dist. Court for S. Dist.*, 482 U.S. 522, 533 (1987). The Hague Convention is recognized as part of the supreme law of the United States. U.S. Const. Art. VI, Cl. 2; *Laker Airways, Ltd. v. Pan Am. World Airways*, 103 F.R.D. 42, 49 (D.D.C. 1984) (the Hague Convention is an international treaty and as such is entitled to be recognized as the supreme law of the land under Article VI, Clause 2, of the United States Constitution).

The Hague Convention's purpose is to facilitate and increase the exchange of information between nations. *Societe Nationale*, 482 U.S. at 534; *Laker Airways*, 103 F.R.D. at 49. The preamble to the Hague Convention states its purpose is to "improve mutual judicial co-operation in civil or commercial matters" and to "facilitate the transmission and execution of Letters of Request." Hague Convention (*see* 23 U.S.T. 2555). *See also Societe Nationale*, 482 U.S. at 534.

The Hague Convention allows courts in one Contracting State to request another Contracting State to "obtain evidence, or to perform some other judicial act" by a Letter of Request. Hague Convention, Ch. I, Art. 1 (*see* 23 U.S.T. 2555). Each Contracting State designates a "Central Authority" to receive requests from courts of other member countries. *Id*. at Art. 2. The Central

Authority then sends the request to the appropriate court or officer to execute the request. *See* Largent Decl., Ex. A.

B. The Documents Sought from the EMA Are Directly Relevant to Plaintiffs' Allegations

The documents retained by the EMA concerning rimonabant are important with regard to plaintiffs' allegations that defendants knowingly or recklessly failed to disclose to investors the link between rimonabant and suicidality. In April 2006, Sanofi submitted an application to the EMA for marketing authorization for rimonabant in Europe under the name "Acomplia." On June 19, 2006, while Sanofi's NDA for rimonabant was still pending with the FDA, at the recommendation of the EMA, the European Union ("EU") approved the sale of rimonabant for treatment of obesity in 25 EU countries. During 2006 to 2009 Sanofi marketed and sold rimonabant as "Acomplia" in several EU countries.

On July 19, 2007, shortly after the FDA's advisory committee recommended that the FDA deny Sanofi's rimonabant application, the EMA issued a press release announcing that its Committee for Medicinal Products for Human Use ("CHMP") recommended that it was inadvisable for patients with ongoing major depression or who were being treated with antidepressants, to continue taking rimonabant because of the risk of psychiatric side effects. Thereafter, in October 2008, the CHMP concluded that risks of depression, anxiety and stress disorders outweighed rimonabant's weight loss benefits and recommended that its marketing authorization be suspended across the EU. The EMA's press release regarding this matter noted that the CHMP's recommendation was based on studies Sanofi completed after June 2006 which showed a doubling of the risk of psychiatric disorders in people taking rimonabant compared to those taking placebo.

On January 16, 2009 the EMA issued a report with the CHMP's recommendation for the suspension of rimonabant's marketing authorization. Based on this recommendation, the EU

withdrew the marketing authorization for rimonabant. The EMA's report presented the scientific conclusions and grounds for the suspension and identified various documents, reports, studies and data the EMA and its committees analyzed and reviewed in assessing the safety of rimonabant, which are relevant to this case. Based on the report, the documents retained by the EMA are highly likely to provide evidence concerning the link between rimonabant and psychiatric disorders, including suicidality, which is a central issue in this case.

IV. CONCLUSION

For all of the foregoing reasons, plaintiffs respectfully request that this Court grant their application and issue the Letter of Request, attached to the Declaration of Laurie L. Largent as Exhibit A. Plaintiffs have provided the Court with a pre-paid envelope addressed to the appropriate central authorities in the United Kingdom. The Court need only sign the Letter of Request and execute the mailing.[3]

DATED: August 17, 2010

Respectfully submitted,

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TRIG R. SMITH
LAURIE L. LARGENT

s/ LAURIE L. LARGENT
LAURIE L. LARGENT

[3] Plaintiffs respectfully request that the Court mail the Letter of Request directly to the appropriate central authorities. In the past, plaintiffs' counsel have experienced resistance from foreign central authorities on the basis that the Letter of Request was not transmitted directly from the requesting court.

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CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2010, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I caused to be mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on August 17, 2010.

s/ LAURIE L. LARGENT
LAURIE L. LARGENT

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Manual Notice List

The following is the list of attorneys who are **not** on the list to receive e-mail notices for this case (who therefore require manual noticing). You may wish to use your mouse to select and copy this list into your word processing program in order to create notices or labels for these recipients.

- (No manual recipients)